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EXAMINER
COLEMAN, BRENDA LIBBY

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1624	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/763,767	Applicant(s) THURSTON et al.
	Examiner Brenda Coleman	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 28, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 3-10, 12, 13, 15-21, 25-38, and 40-55* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 3-10, 12, 13, 15-21, 25-38, and 40-55* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1, 3-10, 12, 13, 15-21, 25-38 and 40-55 are pending in the application.

This action is in response to applicants' amendment filed August 28, 2002. Claims 1, 3, 6, 7, 12, 13, 15-20, 25, 28, 31, 32, 34, 35, 38, 40, 41 and 43-45 have been amended, claims 2, 11, 14, 22-24 and 39 have been canceled and claims 46-55 are newly added.

Response to Amendment

Applicants' arguments filed August 28, 2002 have been fully considered with the following effect:

1. The applicant's amendments are sufficient to overcome the objection to the drawing in the last office action which is hereby **withdrawn**.

2. With regards to the objection to the Arrangement of the Specification, the applicants stated that they "have added the appropriate section headings as suggested by the examiner". However, the section heading which was emphasized in the last office action was not added, i.e. **Brief Description of the Several Views of the Drawing(s)**.

3. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 1-44, labeled 4a) and 4b), the applicants' amendments and remarks have been fully considered but are not found persuasive.

a) The applicants' stated that "the *Dictionary of Science and Technology* defines heterocyclic compounds as cyclic or ring compounds containing carbon atoms and

other atoms, e.g., O, N, S, as part of the ring". Compound claims are the most comprehensible claim and therefore you have to indicate what you mean by the compound in order for it to be known what is being claimed. The patent office recognizes a hetero atom to be N, O, S, Se and Te, however, there are multiple definitions for hetero atom as shown by the definition of hetero atom in Hackh's Chemical Dictionary. Hackh's defines hetero atom as "any atom other than carbon, C, in an atomic ring; e.g., N, O, S, Se, P, As". Katritzky defines hetero atom in addition to N, O, and S in chapter seven as intramolecular hydrogen; metals such as mercury and lithium; boron; silicon, germanium and tin; phosphorus, arsenic, antimony and bismuth; selenium and tellurium; and the halogens. If multiple different definitions of a term exists then the applicant must define exactly what is meant by "hetero".

Variations within peoples minds of hetero (i.e. hetero atom) as to the number and nature of the hetero atoms and the size of the hetero rings must be defined so as to provide adequate written description to the reader. Conception of what the intended heterocyclic ring, may be, should not be left to the reader. The heterocyclic definition presents a problem of lack of clear claiming and support in the specification for the variables sought. Even any combination of atoms, selected from the group consisting of O, S or N, rests specific conception with the reader. Not a fair burden in return for applicants receiving a 17/20 year monopoly.

The possible combinations of any number of hetero atoms, in any combination, in multiple size rings, is quite large, and not shown by applicants to be available starting materials. A Markush listing of intended, conceived of, producible heterocyclic rings is what is needed here. The utility here is pharmaceutical. Declarations of unexpected results are often presented in this art. Applicants breadth of heterocyclic produces many different heterocyclic moieties that could easily affect results. Applicants need to claim what they have demonstrated as a specific fact. Note: In re Wiggins, 179 USPQ 421, 423 (CCPA 1973) held heterocyclic was unclear.

b) The applicants' stated that the "term is understood by those skilled in the art" and that the "specification (page 6, line 5) lists carbonyl and hydroxy groups as two examples". First the phrase "functional group" is unduly functional. Names, structures, and chemical formulas precisely define organic molecules. Attempting to define structure by function is not proper when the structures can be clearly expressed in terms that are more precise. Additionally, it is not sufficient to define a chemical structure solely by its principal biological property. The applicants have not described the meets and bounds of the compounds. It has not been established what the compounds are. Second, the two groups the applicants point to for support, i.e. carbonyl and hydroxy are diverse in that carbonyl is divalent and

hydroxy is monovalent. The variable R is monovalent, thus it is not known how R can be carbonyl.

Claims 1, 3-10, 12, 13, 15-21, 25-35, 38, 40-44 and newly add claims 46-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For reasons of record and stated above.

4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled a), b), c), f), g), h), i), j), k), l), m), o), p), r) and s) which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled d), e), n) and q) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

d) The applicants' stated that "R_2 is defined as R, OH, OR, CO_2H, CO_2R, COH, COR, SO_2R, CN" and "because R is further defined as a lower alkyl group having 1 to 10 carbon atoms .... and optionally containing one or more hetero atoms which may form part of, or be, as a functional group, there is sufficient antecedent basis for this limitation. However, use of the variable R in the definition of R is indefinite. It is not known what is meant by R_2 where R_2 is R and R is CH_2OR.

e) The applicants' stated that "there is sufficient antecedent basis for CH_2OAc in the definition of R. However, use of the variable R in the definition of R is indefinite. It is not known what is meant by R_2 where R_2 is R and R is CH_2OR and the R of the CH_2OR is Ac.

n) The applicants' stated that "one skilled in the art would be able to ascertain which nitrogen protecting groups fall within the scope of R". However, the definition of R'_8 and $R"_8$ where R'_8 and $R"_8$ are as a nitrogen protecting group is broader in scope than that which is defined in R.

q) The applicants' stated that claims 38 and 40-43 have been amended. However, there is no amendment to claim 42.

Claims 4, 5, 30 and 42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

5. With regards to the rejection of claims 38 and 40-43 under 35 U.S.C. § 101, in the last office action, the applicants stated that "this rejection has been obviated by the amendment of claims 38 and 40-43 to set forth steps involved in the process. However, there is no amendment to claim 42.

Claim 42 is rejected under 35 U.S.C. 101 because the claimed recitation of as a use, without setting forth any steps involved in the process, results in an improper definition of as a

process, i.e., results in as a claim which is not as a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). For reasons of record and stated above.

6. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejections labeled paragraphs 7), 8), 9), 10), 11), 12), 13), 14), 15), 16), 17), 18) and 19) in the last office action which are hereby **withdrawn**.

7. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 103, obviousness rejections labeled paragraphs 20), 21), 22), 23), 24) and 25) in the last office action which are hereby **withdrawn**.

8. With regards to the obviousness-type double patenting rejection as being unpatentable over copending Application No. 09/763,813 in the last office action, the applicants stated that "the examiner has not established as a *prima facie* case of obviousness" and that "the examiner has provided no analysis as to the difference between the inventions claims by the conflicting claims compared to as a claim in the instant application, and so to the reasons why as a person of ordinary skill in the art would have concluded that the invention defined in the claims of the present invention is an obvious variant of the inventions defined in the claims of the copending

applications". However, claims 17-21 and 23-25 of copending Application No. 09/763,813 embrace compounds, compositions and method of use of the compounds as claimed herein.

Claims 1, 3-7, 20, 21, 25-27, 29-38, 40-44 and newly added claims 46 and 48-55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-21 and 23-25 of copending Application No. 09/763,813. For reasons of record and stated above.

9. The applicant's arguments are sufficient to overcome the provisional obviousness-type double patenting rejections labeled paragraphs 27 and 28 in the last office action which are hereby **withdrawn**.

In view of the amendment dated August 28, 2002, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is as a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain as a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 31 and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such as a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following reasons apply:

as a) The amendment to the definition of R_7 in claim 31 where R_7 is an electron donating group is not described in the specification.

b) The amendment to claim 38 where "as a method of therapy" was amended to "treating as a condition which can be treated by regulation of gene expression" is not described in the specification.

Applicant is required to cancel the new matter in the reply to this Office action.

11. Claims 38, 40, 41 and 43-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such as a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

HOW TO USE: In evaluating the enablement question, several factors are to be considered. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988); *Ex parte Forman,* 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The nature of the invention in the instant case, has claims which embrace substituted pyrrolo[2,1-c][1,4]benzodiazepin-5-one compounds of the formulae Ia, Ib, II, III and IV. Claims 38, 40, 41, 43 and 44 are to as a method of treating as a condition which can be treated by

regulation of gene expression, method of treating as a gene-based disease, method of treating as a viral, parasitic or bacterial infection, method of treating as a cisplatin-refractory disease, and as a method of inhibiting the growth of cisplatin-refractory cells, respectively, comprising the step of administering as a compound of formulae Ia, Ib, II, III and IV. Any evidence presented must be commensurate in scope with the claims and must clearly demonstrate the effectiveness of the claimed compounds. However, the specification provides no definitive evidence to correlate any one disorder selected from those disclosed in the specification with the instantly disclosed pyrrolo[2,1-c][1,4]benzodiazepin-5-one compounds.

Testing is provided for only as a few of the claimed compounds spanning pages 201-214. Examples should be of sufficient scope as to justify the scope of the claims. However, the generic claims are much broader in scope than is represented by the testing. Markush claims must be provided with support in the disclosure. Markush claims are subject to rejection based upon the lack of supporting disclosure when the "working examples" fail to include written description(s) which teach how to make and use Markush members embraced thereby in full, clear, and exact terms. See In re Fouche 169 USPQ 429. The compounds tested are not seen as adequately representative of the compounds encompassed by the extensive Markush groups instantly claimed for the uses instantly asserted and claimed.

The specification fails to disclose working examples on the use of the pyrrolo[2,1-c][1,4]benzodiazepin-5-one compounds of formulae Ib and II. The absence of working examples is one of the factors to be considered in deciding whether the practice of an invention would

involve undue experimentation. There must be evidence to justify the contention that the claimed compounds can be useful in the treatment of lung, colon, CNS, melanoma, renal and breast cell lines.

In general, pharmacological activity is as a very unpredictable area. In cases involving physiological activity "the scope of the enablement obviously varies inversely with the degree of unpredictability of the factors involved." ***In re Fisher***, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Since this case involves unpredictable *in-vivo* physiological activities, the scope of the enablement given in the disclosure presented here was found to be low.

12. Claims 38, 40, 41 and 43-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such as a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The scope of the method claims are not adequately enabled solely based on the regulation of gene expression or its inhibitory effect on cisplatin-refractory cells provided in the specification. The specification, while being enabling for bacterial infections, does not reasonably provide enablement for treatment of all disorders claimed herein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In addition to other disorders which are difficult to treat these claims call for the treatment of cancer which are capable of being modulated by regulation of gene expression and/or inhibiting the growth of

cisplatin-refractory cells. However, there never has been as a compound capable of treating cancer generally. There are compounds that treat as a range of cancers, but no one has ever been able to figure out how to get as a compound to treat cancer generally, or even as a majority of cancers. Thus, the existence of such as a "silver bullet" is contrary to our present understanding in oncology. Even the most broadly effective antitumor agents are only effective against as a small fraction of the vast number of different cancers known. This is true in part because cancers arise from as a wide variety of sources, such as viruses (e.g. EBV, HHV-8, and HTLV-1), exposure to chemicals such as tobacco tars, genetic disorders, ionizing radiation, and as a wide variety of failures of the body's cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers generally, evidence that the level of skill in this art is low relative to the difficulty of such as a task.

The following is as a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1, 3, 6-10, 12, 13, 15-19, 31, 35-38 and 40-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

as a) Claims 1, 3, 6-10, 12, 35-38, 40-44 and 46 are vague and indefinite in that it is not known what is meant by the proviso where when as a is as a single bond, then R_2 is not $CH=CR^AR^B$, where R^A and R^B are independently selected from COR^C, $CONH_2$, $CONHR^C$, $CONR^C_2$, cyano or phosphonate. At no time is R_2 $CH=CR^AR^B$, where R^A and R^B are independently selected from COR^C, $CONH_2$, $CONHR^C$, $CONR^C_2$, cyano or phosphonate.

b) Claim 6 is vague and indefinite in that it is not known what is meant by the definition of R_2 where R_2 forms part of as a conjugated system with as a double bond of as a pyrrolobenzodiazepine. It is not known which double bond is being referred to, nor which pyrrolobenzodiazepine.

c) Claim 7 recites the limitation "unless the compound is as a dimer" in the definition of R_8. There is insufficient antecedent basis for this limitation in the claim. R_8 can never be H or OR.

d) Claim 8 recites the limitation "unless the compound is as a dimer" in the definition of R_8. There is insufficient antecedent basis for this limitation in the claim. R_8 can never be H, OMe or OCH_2Ph.

e) Claim 9 recites the limitation "unless the compound is as a dimer" in the definition of R_8. There is insufficient antecedent basis for this limitation in the claim. R_8 can never be OR.

f) Claim 10 recites the limitation "unless the compound is as a dimer" in the definition of R_8. There is insufficient antecedent basis for this limitation in the claim. R_8 can never be OMe or OCH_2Ph.

g) Claims 13, 15-19, 35-38, 40-44 and 47 are vague and indefinite in that it is not known what is meant by the definition of R'_2 where R'_2 is selected from: O. "Selected from" is used to describe as a Markush of substituents, for which R'_2 has none. R'_2 is simply one substituent, i.e. O.

h) Claims 31 and 42 are vague and indefinite in that it is not known what is meant by electron donating group.

i) Claims 38, 40, 41, 43 and 44 are vague and indefinite in that the claim provides for the use of claimed compounds, but the claim does not set forth any steps involved in determining which are the diseases capable of being mediated by regulation of gene expression. It is unclear which diseases are mediated by regulation of gene expression. Determining whether as a given disease responds or does not respond to such an inhibitor will involve undue experimentation. Suppose that as a given drug, which has inhibitor properties *in vitro*, when administered to as a patient with as a certain disease, does not produce as a favorable response. One can not conclude that specific disease does not fall within this claim. Keep in mind that:

as a. It may be that the next patient will respond. No pharmaceutical has 100% efficacy. What success rate is required to conclude our drug is as a

treatment? Thus, how many patients need to be treated? If "successful treatment" is what is intended, what criterion is to be used? If one person in 10 responds to as a given drug, does that mean that the disease is treatable? One in 100? 1,000? 10,000? Will the standard vary depending on the current therapy for the disease?

B. It may be that the wrong dosage or dosage regimen was employed. Drugs with similar chemical structures can have markedly different pharmacokinetics and metabolic fates. It is quite common for pharmaceuticals to work and or be safe at one dosage, but not at another that is significantly higher or lower. Furthermore, the dosage regimen may be vital --- should the drug be given e.g. once as a day, or four times in divided dosages? The optimum route of administration can not be predicted in advance. Should our drug be given as as a bolus *iv* or in as a time release *po* formulation. Thus, how many dosages and dosage regimens must be tried before one is certain that our drug is not as a treatment for this specific disease?

C. It may be that our specific drug, while active *in vitro*, simply is not potent enough or produces such low concentrations in the blood that it is not an effective treatment of the specific disease. Perhaps as a structurally related drug is potent enough or produces high enough blood concentrations to treat the disease in question, so that the first drug really does fall within the claim. Thus, how many

different structurally related inhibitors must be tried before one concludes that as a specific compound does not fall within the claim?

D. Conversely, if the disease responds to our second drug but not to the first, both of whom are inhibitors *in vitro*, can one really conclude that the disease falls within the claim? It may be that the first compound result is giving the accurate answer, and that the success of second compound arises from some other unknown property which the second drug is capable. It is common for as a drug, particularly in the field of antibiotics, to work by many mechanisms. The history of psychopharmacology is filled with drugs, which were claimed to be as a pure receptor XYX agonist or antagonist, but upon further experimentation shown to effect as a variety of biological targets. In fact, the development of as a drug for as a specific disease and the determination of its biological site of action usually precede linking that site of action with the disease. Thus, when mixed results are obtained, how many more drugs need be tested?

E. Suppose that our drug is an effective treatment of the disease of interest, but only when combined with some totally different drug. There are for example, agents in antiviral and anticancer chemotherapy which are not themselves effective, but are effective treatments when the agents are combined with something else.

Consequently, determining the true scope of the claim will involve extensive and potentially inconclusive research. Without it, one skilled in the art cannot determine the actual scope of the claim. Hence, the claim is indefinite.

j) Claim 45 recites the limitation "methylidene" in the nomenclature of the species. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is as a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> as a person shall be entitled to as a patent unless -
>
> (as a) the invention was known or used by others in this country, or patented or described in as a printed publication in this or as a foreign country, before the invention thereof by the applicant for as a patent.
>
> (b) the invention was patented or described in as a printed publication in this or as a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 50-55 are rejected under 35 U.S.C. 102(as a) as being anticipated by Gregson et al., Chem. Commun. Gregson teaches the compounds, compositions and method of use of the compounds of formula II where R_6 is hydrogen, R_7 is methoxy, R_8 forms the dimer through the bridge -O-$(CH_2)_3$-O-, R_9 is hydrogen, and R'_2 is CH_2. See example 1.

15. Claims 20, 38, 40-44 and 48 are rejected under 35 U.S.C. 102(as a) as being anticipated by Suggs et al., Tetrahedron Letters. Suggs teaches the compounds, compositions and method of

use of the compounds of formula III where R_6 is hydrogen, R_7 is amino, and R_8 and R_9 are hydrogen. See example 8.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays from 8:30 AM to 5:00 PM, on Tuesdays from 8:00 AM to 4:30 PM, on Wednesday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of as a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brenda Coleman

Brenda Coleman
Primary Examiner AU 1624
November 14, 2002